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Dockets Management Branch (HFA-305) Food and Drug Administration 5630 Fishers Lane, Room 1061 Rockville, MD 20852

This letter is in reference to Docket No. 98P-0504, concerning the CSPI petition to FDA to establish a performance standard for Vibrio vulnifucus.

It is the concern of Tampa Maid that all products that represent the seafood industry be safe for consumption by healthy, as well as health compromised, individuals. Those who choose to eat raw seafood take risk that not only can harm themselves, but can, and has harmed the reputation of the seafood industry as a whole.

We would support a regulation that would require a pasteurizing process for only oysters that are to be consumed raw, as on the half-shell. This is primarily shell stock.

Oysters that are shucked and sold to processors for further processing should not require a pasteurizing step. This product is to be breaded, frozen, and fully fried by the end user before consumption.

Requiring that shucked oysters, for further processing as described herein, be pasteurized would only add to the initial processing cost, reduce yield on pack, and both results would drive up cost. The texture would most likely be adversely affected and later exacerbated by reconstitution in a deep fat fryer. As for raw shucked oysters to be further processed, a simple tag "not for raw consumption" should suffice to protect the public. The public must take some responsibility in only consuming pasteurized oysters in the shell.

FDA should determine the infective dose of Vibrio v. and establish a tolerance. A "non-detectable" standard may be unnecessarily stringent and only increase cost without further benefit to the public.

Once a standard is determined, it should apply to any molluscan shellfish that has demonstrated a propensity to cause illness when consumed raw.

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As for the benefits, the health compromised will be ensured safe shell stock that can be consumed raw. The seafood industry in general will regain its rightful reputation as one of the safest protein foods when compared to beef or poultry.

Carl Tamborello

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Cc: George Watkins, Chairman and CEO

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Ed Smith, Sr. VP, Finance





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